Comments of the

the Alkylphenols & Ethoxylates Research Council

on the

Proposed Rule for a Significant New Use Rule

on Certain Nonylphenols and Nonylphenol Ethoxylates

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Executive Summary

The Alkylphenols & Ethoxylates Research Council (APERC) appreciates this opportunity to comment on the EPA's Proposed Significant New Use Rule on Certain Nonylphenols and Nonylphenol Ethoxylates. (U.S EPA, 2014, October 1). APERC is a North American organization whose mission is to promote the safe use of alkylphenols (APs), alkylphenol ethoxylates (APEs), including nonylphenols (NP) and nonylphenol ethoxylates (NPEs) through science-based research, product stewardship and outreach efforts, within the framework of responsible chemical management. For more than twenty five years, APERC and its member companies have been actively engaged in the conduct and review of toxicological, environmental fate and ecotoxicity research on NPs and NPEs, including understanding their chemical structures, nomenclature and chemical and physical properties. Therefore, APERC can contribute substantively as a resource to EPA on these compounds.

Since the Proposed Significant New Use Rule (SNUR) was published, APERC has received many inquiries from throughout the broad supply chain related to this family of chemicals, including companies that are not APERC members as well as other organizations representing manufacturers, processors and end users of NP and NPE. The proposed SNUR touches on a long-standing chemical nomenclature and CAS number issue concerning branched and linear NP and their derivative NPE. The Proposed SNUR would apply to all "new uses" of thirteen CAS numbers for NP and NPE (Table 1 in the Proposed SNUR) that EPA believes are not currently in commerce in the United States. The Proposed SNUR would also apply to uses "other than as a chemical intermediate or epoxy cure catalyst" for two NP CAS numbers (Table 2 in the Proposed SNUR), which are known by EPA to be in commerce in those uses.

As noted in the Proposed SNUR, APERC worked with EPA in the development of a Testing Consent Order in 1990 and confirmed that industrially produced NP is a substance comprised mostly of branched C9-alkyl phenols. (EPA, 1990, February 21) APERC has publicly provided information about the manufacture of NP and NPEs and acknowledged that numerous CAS numbers and nomenclatures with differing specificity in describing branching are used to

describe these compounds. This includes many of the CAS numbers listed in the Proposed SNUR.

While APERC is familiar with the nomenclature issues raised in the Proposed SNUR, this may be new for some companies in the NP and NPE supply chain. This may be particularly true for small business entities not as familiar with TSCA nomenclature issues in general. In addition, many of the NP and NPE CAS numbers listed in the Proposed SNUR are recognized and accepted by other EPA programs and other US and international governmental authorities in the global market, which provides a valid basis for their use in commerce for different regulatory purposes and in general. More importantly, many of the NP and NPE CAS numbers listed in the Proposed SNUR are in fact in commerce and have been for decades and, regardless of the specificity of their descriptions, are viewed synonymously in the market.

The comments below provide more detailed explanation of the following concerns that APERC has regarding the Proposed SNUR and the process used by EPA to develop it.

- EPA is using the incorrect authority under TSCA by using a Proposed SNUR to collect use information about certain NP and NPE CAS numbers; furthermore an initial effort to conduct outreach and communicate with industry would likely have resulted in more useful information with less burden and confusion among the producers, processors and users of the compounds and CAS numbers of interest;
- The method by which EPA evaluated whether the NP and NPE CAS numbers listed in the Proposed SNUR are in use in the US was cursory and did not meet standards of reasonable due diligence necessary to support its consideration under TSCA Section 5(a)(2);
- The majority of the NP and NPE CAS numbers listed in the Proposed SNUR are recognized by other governmental agencies and other chemical industry lists and databases; in addition most have been identified in at least some uses based solely on an initial, though not comprehensive survey, by APERC; and

- Regardless of which nomenclature and CAS numbers are used to describe NP and NPE, the reasoning provided in the Proposed SNUR to establish a need for concern about their risk to the environment is insufficient to justify a SNUR; the lack of rigor in EPA's reasoning is demonstrated in part by incorrect citation of its own Water Quality Criteria for NP.

Due to the deficiencies in the process used to develop the Proposed SNUR for certain NP and NPE CAS numbers, and the fact that the majority of CAS numbers listed in the Proposed SNUR have been reported to APERC as being in commerce and use in the U.S., APERC recommends that EPA should completely withdraw the Proposed SNUR. A more robust effort is needed to determine a comprehensive use profile for the NP and NPE CAS numbers listed in the Proposed SNUR. In addition, EPA should work to resolve confusing nomenclature issues with NP and NPE not through the use of a "dead chemical" SNUR, but rather through development of nomenclature guidance for these compounds and communication with industry. As the U.S. based organization representing these compounds, APERC can provide assistance to EPA in such efforts.

COMMENTS

1.0 EPA is using incorrect authority under TSCA by using a Proposed SNUR to collect use information about certain NP and NPE CAS numbers; furthermore an initial effort to conduct outreach and communicate with industry would likely have resulted in more useful information with less burden and confusion among the producers, processors and users of the compounds and CAS numbers of interest.

EPA is proposing to designate any use of the of thirteen NP and NPE CAS numbers listed in Table 1 of the Proposed SNUR and any use, other than as an intermediate or an epoxy cure catalyst of the two NP CAS number listed in Table 2 as a significant new use. The Proposed SNUR would apply to the uses that were not ongoing at the time of the Proposed Rule and EPA requests information about whether anyone is currently using these chemicals in a manner that is not described in the Proposed Rule.

A primary reason for the Proposed SNUR is that EPA believes that the listed CAS numbers do not describe industrial grade NP and NPE; rather they describe linear or nonspecific NP and NPE. However, these CAS numbers have actually been in use, albeit perhaps under a less than fully descriptive name, due to their listing on the TSCA inventory and/or recognition by other governmental authorities, in some cases for decades. Hence, regardless of the accuracy of the nomenclature, many of the listed CAS numbers are "in use" and a SNUR is not an appropriate approach to resolving CAS number and nomenclature issues under TSCA.

APERC believes EPA used incorrect authority under TSCA by issuing a Proposed SNUR to collect information about the commercial status and use of certain NP and NPE CAS numbers. TSCA Section 8(a) gives EPA the broad authority to require, by rulemaking, manufacturers (includes importers) and processors of chemical substances to report such data as EPA may reasonably require to carry out the TSCA mandates. Examples of information that can be required to be reported include chemical identity and categories of use. Following collection of use information using under TSCA 8(a), the Agency could then more effectively determine whether and in what manner it may wish to issue a SNUR. EPA acknowledged in the Proposed Rule that TSCA 8(a) was available to collect information requested in the Proposed SNUR. However, review of EPA's regulatory objectives as described in Section IIIB of the Proposed SNUR indicate that EPA's objective was in fact to issue a SNUR; therefore use TSCA 8(a) to collect chemical identify and use information was rejected because it would not meet EPA's objective. APERC views the approach taken in the Proposed SNUR (i.e., proposing a "dead chemical" SNUR to collect use data) as having the effect of subverting the authority and undermining the intention of TSCA while imposing a burden on industry to respond with all known uses of listed compounds, some of which have been legally in use for decades, within a short comment period.

An initial effort by EPA to conduct outreach and communicate with industry would likely have resulted in more useful information with less burden and confusion among the producers, processors and users of the compounds and CAS numbers of interest.

2.0 The method by which EPA evaluated whether the NP and NPE CAS numbers listed in the Proposed SNUR are in use in the US was cursory and did not meet standards of reasonable due diligence necessary to support its consideration under TSCA Section 5(a)(2).

Development of the Proposed SNUR did not include an adequate search to determine whether the NP and NPE CAS numbers listed in it were in use in the U.S. It relied only on one year's reporting (2012) under the Chemical Data Reporting (CDR) Rule, the Household Products Database (HPD) and the Consumer Product Information Database (CPID) to determine whether the CAS numbers in the Proposed SNUR are active in commerce. Unfortunately, the CDR will not reflect production and processing of most NPEs because they are polymers, which are exempt from CDR reporting. In addition, the CDR will not reflect processing of NP or NPE at levels less than the 25,000 pound threshold for reporting under the CDR. Therefore, a lack of reporting under the CDR for the compounds/CAS numbers listed in the proposed SNUR does not equate to a lack of commercial production and use.

In addition, the other two databases used in development of the Proposed SNUR relate only to household and consumer products and will not reflect use of chemicals for industrial and other uses outside of those categories. It should also be noted that the HPD and the CPID do not assert to be accurate, current or complete at any particular point in time. (NLMHPD, 2014; CPIA, 2014)

The inadequate effort by EPA to establish the commercial relevance and uses of the NP and NPE CAS numbers listed in the Proposed SNUR resulted in a burden being placed on industry to disprove its contentions within the short comment timeframe for the Proposed SNUR, even considering the 45 day extension granted by the Agency. Communicating throughout the supply chain for these chemicals, which have been in commerce for decades, was challenging in the time available and APERC does not consider that every use of each of the listed NP and NPE CAS numbers has been identified in these comments. This is especially of concern relative to uses by small businesses, which may not have been aware of the proposed SNUR or have familiarity with chemical and TSCA nomenclature issues.

As noted above, it is APERC's view that an effort by EPA to conduct outreach and communicate with industry would likely have resulted in more useful information with less burden and confusion among the producers, processors and users of the compounds and CAS numbers of interest.

3.0 The majority of the NP and NPE CAS numbers listed in the Proposed SNUR are recognized by other governmental agencies and other chemical industry lists and databases; most have been identified in at least some uses based solely on an initial, though not comprehensive survey by APERC.

Publicly available sources identify some of the listed CAS numbers as being used in commerce, including APERC's website at www.aperc.org. APERC conducted a search of the Arial database (ADM, 2015), a comprehensive database of chemical names, CAS numbers and their listings under various governmental and nongovernmental authorities. Tables 1 and 2 (attached to these comments), which correspond to those in the Proposed SNUR, list the other names (i.e., synonyms) along with regulatory and other listings found in the Arial database for each CAS RN. These other listings indicate recognition and acceptance of these CAS numbers as valid by the US Food and Drug Administration, the Canadian Domestic Substance List (DSL) and even EPA's own Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and Emergency Planning and Community Right-To-Know Act (EPCRA) programs. In fact, on September 20, 2014, the day before the Proposed SNUR for certain NP and NPE CAS numbers was published in the Federal Register, EPA published a Final Rule in the Federal Register that added three of the NP CAS numbers in the Proposed SNUR to the Toxics Release Inventory, indicating that EPA expects the NP CAS numbers are likely to be in use and reported in the US. (EPA, 2014, September 30)

In an APERC survey of the supply chain for NP and NPE, which was not comprehensive due to time constraints and the complexity of the supply chain, nine of the fifteen CAS numbers in the Proposed SNUR received responses as being in commercial use. Since the survey was not comprehensive it is entirely possible that other uses of these CAS numbers are ongoing and were not reported. It is also possible that some of the CAS numbers, which had no uses reported to

APERC, are in fact in use. APERC is aware that other trade associations and individual companies will be providing comments to EPA regarding ongoing uses of some of the listed NP and NPE CAS numbers.

4.0 Regardless of which nomenclature and CAS numbers are used to describe NP and NPE, the reasoning provided in the Proposed SNUR to establish a need for concern about their current or future risk to the environment is insufficient to justify a SNUR; the lack of rigor in developing the justification is demonstrated in part by incorrect citations of EPA's own Water Quality Criteria for NP.

EPA notes in the Proposed SNUR for certain NP and NPEs that, "consistent with EPA's past practice for issuing SNURs under TSCA Section 5(a)(2) EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use." However, there is an expectation that there will be an effort to verify and consider the data presented in the Proposed SNUR. Following are several deficiencies and oversights with the justification for the Proposed SNUR for certain NP and NPE CAS numbers.

4.1 The Proposed SNUR for certain NP and NPE incorrectly characterizes NP and NPE as "persistent".

The Proposed SNUR for certain NP and NPE incorrectly characterizes these substances as "persistent". This is troubling since "persistent" has a very specific definition in various international regulatory fora and robust governmental assessments conducted by the European Union, Environment Canada, Washington State and the state of Oregon have assessed the persistence of these compounds and determined they do not meet these criteria for "persistent". These assessments, which were specific to the properties of persistence and bioaccumulation, concluded NP and NPE are not persistent or bioaccumulative. (ECB, 2003; EC, 2006; WA DoE, 2006, January; OR DEQ, 2009) More recent weight-of-evidence based review papers also found that the weight-of-evidence supports half-lives for NP and NPE of less than 40 days and concluded that these compounds do not meet any US or international definitions for "persistent". (Staples, 2008, Klecka, 2008) Even EPA's recent TSCA Work Plan for Chemical Assessments:

2014 Update ranks NP and NPEs as a level 2 (half-lives between 2 and 6 months) for persistence based on an initial hazard assessment. (EPA, 2014, October)

4.2 The Proposed SNUR for certain NP and NPE incorrectly cites EPA's own final ambient WQC for NP, which indicates the lack of rigor in the development of its justification.

The Proposed SNUR for certain NP and NPE notes that "available data indicate that these chemical substances are highly toxic to fish and invertebrates, causing lethality on an acute basis and effects on survival, growth , development, metabolism, reproduction and fecundity with low level chronic exposure". It also expresses concern that NP and NPE "can potentially cause ecological effects on all trophic levels of aquatic species exposed".

The Proposed SNUR states "EPA has established water quality criteria for NPs of 6.6 micrograms per liter (µg/L) for acute exposures and 1.7 µg/L for chronic exposures." Unfortunately, these are not the correct values for EPA's WQC for NP.

EPA did finalize ambient Water Quality Criteria for NP in 2006. (US EPA, 2005; US EPA 2006) The EPA WQC provide guidelines to states for the development of state Water Quality Standards under the Clean Water Act. When monitoring indicates an exceedance of state WQS, regulatory mechanisms exist under the National Pollutant Discharge Elimination System (NPDES) to enact controls.

The following table provides the final US EPA WQC for NP.

Table 3 U.S. EPA Aquatic Life Ambient Water Quality Criteria for Nonylphenol
(US EPA, 2005; US EPA, 2006, February 23)

Freshwater (µg/L)		Saltwater (µg/L)	
Acute	Chronic	Acute	Chronic
28	6.6	7	1.7

EPA Aquatic WQC are derived such that they are protective of acute and chronic effects, including survival, growth and development, and reproduction in aquatic species across

numerous taxonomic levels including fish and other vertebrates, invertebrates, and algae. Therefore, the concern expressed for effects in aquatic organisms in the Proposed SNUR are addressed across all taxonomic groups as stated in the guidelines for development of EPA's WQC. In addition, the NP WQC document notes "the ability of nonylphenol to induce estrogenic effects has seldom been reported at concentrations below the freshwater final chronic value", which is 6.6 µg/L. (EPA, 2005)

In a review paper by Coady et al, (2010) ecotoxicity studies on NP, which were published after the finalization of the EPA WQC for NP, were found to support the value of the EPA chronic WQC for this compound in freshwater and saltwater environments. (Coady, 2010)

The Proposed SNUR document is correct in noting that EPA has not established WQC for NPEs; however Environment Canada developed Toxicity Equivalence Factors (TEFs) for NPEs and its degradation intermediates, which are presented in Table 4 below. (EC, 2002) These can be used with EPA's WQC for NP to assess the hazard and risk for NP and NPE.

Table 4: Canadian Toxicity Equivalence Factors for NPE Degradation Intermediates

Compound	TEF relative to NP
NP	1
NPnEO ($1 < n < 8$)	0.5
NPnEO ($n > 9$)	0.005
NP1EC	0.005
NP2EC	0.005

4.3 The Proposed SNUR for certain NP and NPE CAS numbers does not provide sufficient basis for concern to warrant a SNUR, regardless of the nomenclature used to describe these compounds.

As summarized in Table 5 below, with the exception of data from the study published by Bennett et al., in 1983 (over 30 years ago) effluent and surface monitoring data presented in the Proposed SNUR for NP and NPE are well below the EPA WQC for NP and the corresponding hazard quotients are well below 1.0. Rather than providing justification for a SNUR under TSCA Section 5(a)(2), the data presented in the Proposed SNUR provides confidence that current and

existing uses of NP and NPE (regardless of CAS number) do not represent a risk to fish and aquatic species in U.S. surface waters.

Table 5: Surface Water and Effluent Monitoring Data as Provided in Proposed SNUR for Certain NP and NPE Compounds Compared to US EPA chronic freshwater WQC for NP

Reference	Analyte	Monitoring Location	Concentration Range	Hazard Quotient*	Comment
Shackelford, W.M. et al., (1983)	NP	Localized industrial discharges	NP 2 – 1,617 µg/L	0.3 – 245	WQC do not apply directly to effluent so these hazard quotients are conservative. These data are also over 30 years old and not reflective of current use patterns .
Bennett, E.R. and Metcalf, C.D. (1997)	NP	Great Lakes	0.1 – 0.92 µg/L	0.02 – .14	
Rice, C.P. et al (2003)	Total NP+NPE	Ohio River	0.13 – 1.0 µg/L	0.02 – 0.15	NP WQC does not apply to total NP+NPE; therefore hazard quotient as calculated here is conservative
Ferry, M. (2013		Minnesota Lakes	0.020 µg/L max	0.003	

* Hazard Quotient calculated as ratio of concentration to US EPA chronic freshwater WQC (6.6 µg/L)

4.4 Additional monitoring data not mentioned in the Proposed SNUR for certain NP and NPE along with market trends indicating decreasing use of NPEs, also indicate a low likelihood of risk from these compounds in U.S. waters currently or in the future.

Although not mentioned in the Proposed SNUR, a paper by Klecka et al. (2007) conducted an assessment of surface water and/or sediment monitoring studies available in the published or publicly available literature to develop a statistical understanding of exposures to alkylphenol ethoxylates (APE), including NPE and NP in US surface waters. A literature search was conducted to identify environmental monitoring studies published during the 15 year period between 1990 and 2005, which contained information on surface water and/or sediment concentrations of APE and its metabolites in US waters. Nineteen reliable monitoring studies, most of which were conducted by the US Geological Survey (USGS), were reviewed and the highest concentrations of all NPE metabolites were generally observed for rivers in heavily

urbanized or industrialized locations with average concentrations of 1.7 µg/L, 1.2 µg/L, 2.3 µg/L, and 8.1 µg/L for NP, NPE1, NPE>1, and nonylphenol ethoxycarboxylate (NPEC) respectively reported. Klecka et al. (2007) reported NPE>1 as a group because the US Geological Survey (USGS), which provided much of the data analyzed in this paper, frequently reported in this manner. However, a review of the database that catalogued all of the raw data analyzed by Klecka et al. (2007) confirmed that the majority (87%) of the data points categorized as NPE>1 do in fact represent concentrations of NPE2. (Klecka, G.M., 2009, August).

Klecka et al. (2007) conducted an assessment of the aggregate exposure to APE and its metabolites measured in US surface waters. The authors relied on the US EPA WQC for NP to establish the benchmark for environmental safety in US waters and the TEFs developed by Environment Canada (2002) to calculate the relative contribution of NPE metabolites and the aggregate toxicity of NP and other NPE degradation intermediates. The authors also assumed that the toxicity interaction between the various NPE metabolites was additive. Their conservative evaluation of aggregate exposure during the period from 1990 to 2005 to all APE degradation metabolites - not just NPE degradants - concluded that 97% of the samples contained aggregate NP-equivalent concentrations which were below the EPA chronic freshwater WQC of 6.6 µg/L and suggested that on a nationwide basis, the likelihood of surface water concentrations exceeding the chronic EPA WQC for NP was low.

Klecka et al. (2007) also used the available data to examine changes in reported concentrations of NPE metabolites in surface water in the U.S. generally over a 15 year sampling period from 1990 through 2005. While noting that the data were drawn from a diverse set of studies with different sampling strategies and analytical methods, the authors found that maximum concentrations varied widely; however, the mean and 90th percentiles for concentrations of NPE and its metabolites remained relatively constant during this time period. Therefore, it was assumed that any apparent shifts in maximum concentrations represented a bias in sampling locations toward effluent-dominated streams rather than an increase in emissions of NP/NPE.

The Proposed SNUR for certain NP and NPE CAS numbers expresses concern that future manufacturing or processing of the fifteen listed NP and NPE CAS numbers "could have the potential to significantly increase the magnitude and duration of environmental exposures"; however the findings in Klecka et al, (2007) along with market trends, which indicate the sales of

this family of chemicals is declining, do not support this concern. Consumption of alkylphenol ethoxylates, which is considered to be primarily (>85%) NPE, in North America (including the U.S., Canada and Mexico) dropped by 44.8% between 2004 (232,000 tons) and 2013 (128,000 tons). (Colin A. Houston & Associates, Inc., 2006, 2013) The drop in the US was influenced by voluntary initiatives under the U.S. EPA Design for Environment Program and market pressures due a policy announcement by Wal-Mart in 2006 to restrict the use of NPEs in cleaning and laundry products that it sells. Therefore, the likelihood of significant new exposure or risk from future new uses of the NP and NPE CAS numbers in the Proposed SNUR is low.

5.0 EPA should completely withdraw the Proposed SNUR for NP and NPEs and embark on a more robust effort to determine the commercial status and use profile of these compounds if that is necessary.

Due to the inadequate process used to develop the Proposed SNUR for certain NP and NPE CAS numbers, and the fact that the majority of CAS numbers listed in the Proposed SNUR have been reported to APERC as being in commerce and use in the US, APERC recommends that EPA should completely withdraw the Proposed SNUR for certain NP and NPEs. EPA should embark on a more robust effort to determine the commercial status and use profile for the NP and NPE CAS numbers listed in the Proposed SNUR, if that information is stilled viewed as necessary after the comments in response to the Proposed SNUR are reviewed. APERC strongly recommends outreach and communication with industry as at least an element in such an effort and, as the U.S. based organization representing these compounds, can provide assistance.

6.0 EPA should work to resolve confusing nomenclature issues with NP and NPE not through the use of a "dead chemical" SNUR, but rather through development of guidance and communication with industry.

The basis of the Proposed SNUR for certain NP and NPEs is EPA's belief that linear NP and NPEs are not produced. However, the linear and nonspecific CAS numbers for these compounds are in use and have been for decades. Rather than addressing this situation by issuing a "dead

chemical" SNUR, EPA should develop nomenclature guidance and communicate with industry on approaches to achieve inventory corrections. This approach will surely assist in addressing confusing nomenclature and CAS number issues with this chemical family more directly and with less resources and burden on industry and EPA.

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